The most beautiful words in the English language?

Language expert Wilfred Funk once published a list of what he thought were the ten most beautiful words in English. His choices: dawn … hush … lullaby … murmuring … mist … luminous … chimes … golden … melody … and, tranquil.

From my point of view as a business owner I have a list of beautiful words which are a little bit different: Purchase order … Check enclosed … Innovation … Quality … ISO9001 … ISO10012-1 … Accuracy … Accuracy Requirements … Service … Customer Satisfaction …

This background information is not focusing on “… Purchase order … Check enclosed “… but all the other beautiful words which are the cornerstones in IBP’s philosophy.

We hope you enjoy this installment of our background information as much as we enjoy writing it.

Best regards,
Werner Pfingstmann
pfingstmann@ibpmt.com

Industry News

B.Braun Dialog and IBP Meter HDM99 now talk to each other

The popular B. Braun “Dialog” Dialysis Machine comes with a new AutoCal feature starting from software release 6.2 and newer to support the calibration of pressure, conductivity and temperature.

With this new software release the Dialog can communicate with the state of the art IBP Dialysis Meter HDM99 version 3.6 and the brand new HDM99XP. Technicians will love this feature because the Dialog machine in Service Mode automatically detects when an HDM99 is connected and displays the HDM reading on the Dialog screen as the reference value. The technician simply confirms this reference value by pushing a button when it is within the required range and the Dialog saves it automatically. This is the next frontier in the advance of hemodialysis machine calibrations.

Thus a possible error of wrong data entry is reduced and the calibration of the Dialog is even easier.

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News from USA

Conductivity Standard Solutions are Medical Devices in USA

IBP has received FDA 510(k) clearance of its Conductivity Standard Solution

The only manufacturer with FDA clearance for conductivity standard solutions for hemodialysis.*

IBP Medical Inc. proudly presents MeterCare™, a complete range of high precession Conductivity Standard Solutions.

Intended use
The “Conductivity Standard Solution MeterCare” may be used to calibrate conductivity reference meters used to test the dialysate, dialysate concentrate and water treatment systems used with dialysate delivering systems.

Product Range
MeterCare ranges from 46.7 μS/cm to 190 mS/cm and includes TDS standard solutions. MeterCare may be used with any type of conductivity meter. MeterCare has a substantially higher accuracy than any competing product available.

Do you have a bug in your center?
You are using conductivity standard solutions to calibrate conductivity meters, right? This reference material may be a bug. Conductivity reference solutions for meters used in dialysis are required to have an FDA clearance, but most companies selling conductivity references solutions in dialysis do not have it. Does your current supplier have the FDA clearance? If you fear the worst you are right. You have been using medical products for years without even realizing the potential consequences. Is the violation of the laws a bug? That is an important question to ponder.

Best regards,
Christopher Weed
Chris@ibpmedical.com

Service
As MeterCare is a medical product it comes with a detailed User Guide. Due to the high cost of manufacturing medical products with high accuracy, the price for this product is higher than a standard solution for industrial applications as has typically been used in hemodialysis. Are your patients worth a slight additional investment in accuracy and quality? But the higher price includes a higher level of service. For example if you have an unopened bottle of MeterCare which has passed its expiration date, we’ll gladly replace up to five bottles a year free with proof-of-purchase.

Chain of Accuracy
Did you ever ask yourself what accuracy a conductivity standard solution needs to have to calibrate a meter used in dialysis?
In accordance with the standard ISO 10012-1 “General Quality Assurance Requirements for Measuring Equipment” every level in the calibration chain needs to have a at least three times higher accuracy than the previous level. Please find below the chain of accuracy for conductivity of a dialysis machine.

<table>
<thead>
<tr>
<th>Conductivity Accuracy of the Dialysis Machine</th>
<th>Required Accuracy of the Dialysis Meter</th>
<th>Required Accuracy of the Reference Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>±0.1 mS/cm</td>
<td>±0.033 mS/cm</td>
<td>±0.011 mS/cm</td>
</tr>
</tbody>
</table>

The conclusion is that the accuracy of conductivity reference solutions needs to have an accuracy of at least ±0.01 mS/cm at 14 mS/cm which is ±0.0714%. This accuracy results in a measurement uncertainty of around ±0.15%. Only IBP manufactures standard solutions that meet these high levels of accuracy.

*See for yourself at www.fda.gov. The FDA database lists only three companies that have ever filed a 510(k) for conductivity solutions. The first two, in 1985 and 1986, are no longer on the market. IBP is the only company listed that currently provides standard solutions with FDA 510(k) clearance to your facility purchasing solutions that are in accordance with FDA standards.

Bugs in dialysis?
Why do we say computers have a bug in them? In 1945, a computer at Harvard malfunctioned. Grace Hopper, who was working with the computer, investigated the problem and found a moth in one of the circuits. She removed the bug with tweezers. From then on, when something went wrong with a computer, it was said to have a bug in it.

You are using conductivity standard solutions to calibrate conductivity meters, right? This reference material may be a bug. Conductivity reference solutions for meters used in dialysis are required to have an FDA clearance, but most companies selling conductivity references solutions in dialysis do not have it. Does your current supplier have the FDA clearance? If you fear the worst you are right. You have been using medical products for years without even realizing the potential consequences. Is the violation of the laws a bug? That is an important question to ponder.

Best regards,
Christopher Weed
Chris@ibpmedical.com
News from Europe

Dialysis Meters re-classified as Medical Devices in EU

The demands made on dialysis measuring equipment are growing. What effect does this have on the dialysis technician and companies involved?

Decision

On July 30, 2002, the regional governing authority in Hannover, Germany gave a formal written decision to IBP Instruments GmbH that measuring instruments for the maintenance of dialysis machines are regarded as accessories to dialysis machines and according to §3 Nr.9 MPG, are classified as medical devices. (MPG is the German law incorporating European Council Directive 93/42/EEC concerning medical devices.)

The result is that Dialysis Meters are now subject to medical device regulations throughout the EU. IBP has been called upon to submit the necessary supporting documentation to prove conformity with the MPG.

IBP has complied with the request and the HDM97 and HDM99 instruments are now registered for use with dialysis machines as medical devices.

Effect

This regional decision has far-reaching consequences for the whole of Europe and all dialysis centers and companies involved in the repair and calibration of dialysis units.

One important question arises for the users and for clarification, IBP has put forward the following query to the regional governing authority (BR).

As the answers are not completely applicable for all European countries we have included our comments where appropriate.

IBP: Is there a transition deadline for those dialysis measuring instruments which do not conform to the MPG as registered equipment?

BR: Medical equipment is equipment which was previously defined as being part of machine safety and falls specifically under medical equipment safety regulations. Transition period and time limits have run out. Their use now falls fully under the medical device regulation.

IBP: Comment to the BR answer: As the medical regulations in different countries have been released at different times the deadline is little bit different in different countries. The situation in Germany is: Dialysis measuring equipment which does not conform to the medical device regulations and bought after June 30, 2002 can no longer be used. Using this measurement equipment is a violation of the medical device regulation and can result in prosecution. Monitoring is carried out by the trade supervisory board and calibration authorities.

What comes next?

Find out if your dialysis meters are registered as medical device by checking the CE Mark. Registered products have a number next to the mark. The IBP CE Mark for medical devices is reproduced below. To avoid future problems, only use meters registered as medical devices.

IBP Meters

The IBP dialysis measuring equipment has been classified as belonging to group IIa. New units will carry the CE mark as described.

HDM80

This unit cannot be upgraded. This should be acceptable considering the age of the model.

HDM90, HDM96, HDM97 and HDM99

Can all be upgraded. Hard and software will be updated to the latest version and the units will get the CE mark for medical devices.

Further information on upgrades and prices can be found on the Internet: www.ibpmt.com.
Measurement Accuracy Requirements for Dialysis Meters used in the Calibration of Dialysis Machines

What kind of measuring equipment is appropriate for the calibration of dialysis machines?

Very few manufacturers of dialysis machines give recommendations for the use of specific measuring equipment. Our research has found only the following recommendations shown in hemodialysis machine documentation: B. Braun IBP HDM99 Gambro MESA 90DX

In order to make such a recommendation the manufacturers making the recommendation must first carry out a risk analysis. A risk analysis must be carried out by the end user in cases when the dialysis machine operators use dialysis meters for calibration that are not recommended by the machine manufacturer. Have you done this for your facility?

The most important question in a risk analysis is: **What measuring accuracy is required in measuring equipment for the calibration of dialysis machines?**

In the Guidance Section of the international standard ISO 10012-1 “General Quality Assurance Requirements for Measuring Equipment” is shown detailed information on the subject: "The error attributable to calibration should be as small as possible. In most areas of measurement, it should be no more than one third and preferably one tenth of the permissible error of the confirmed equipment when in use."

This is an internationally applicable standard. This means that the measuring equipment for the maintenance of dialysis units must have a measuring accuracy which is at least three times higher than the measuring accuracy of the dialysis machine.

In some European countries this rule is explicitly part of the Medical Device Regulation.

Are your present meters in compliance with these critical quality standards?

The next table shows the accuracy of the conductivity and temperature measurements of popular dialysis machines.

Measuring Accuracy of Dialysis Machines

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Machine</th>
<th>Conductivity</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Braun</td>
<td>Dialog</td>
<td>±0.2 mS/cm</td>
<td>+0.5/-1.5°C</td>
</tr>
<tr>
<td>FMC</td>
<td>4008S</td>
<td>±0.1 mS/cm</td>
<td>±0.5°C</td>
</tr>
<tr>
<td>Gambro</td>
<td>AK100/200</td>
<td>±0.1 mS/cm</td>
<td>+0.5/-1.5°C</td>
</tr>
<tr>
<td>Hospal</td>
<td>Integra</td>
<td>±0.2 mS/cm</td>
<td>±0.5°C</td>
</tr>
<tr>
<td>Nikkisho</td>
<td>DBB-03</td>
<td>±0.1 mS/cm BC</td>
<td>±0.8°C</td>
</tr>
</tbody>
</table>

The displayed accuracy measurements apply to 14 mS/cm. The values printed in red lie outside the minimal needed accuracy according to ISO 10012-1 (MAAI). These values are calculated as:

MAAI (Minimum accuracy according to ISO 10012-1) = Measuring Accuracy Dialysis Machine / 3

Measuring Accuracy of Meters

The following dialysis meters are included in the next chart:

- IBP Medical HDM97 and HDM99
- MESA 90DX™ also valid for the Gambro Meter
- MESA NEO-2™, also valid for meters from Automata

The displayed accuracy measurements apply to 14 mS/cm. The values printed in red lie outside the minimal needed accuracy according to ISO 10012-1 (MAAI). These values are calculated as:

MAAI (Minimum accuracy according to ISO 10012-1) = Measuring Accuracy Dialysis Machine / 3

### Chart of Dialysis Machines and Meters

<table>
<thead>
<tr>
<th>B. Braun</th>
<th>FMC 4008S</th>
<th>Gambro AK100/200</th>
<th>Hospal Integra</th>
<th>Nikkisho DBB-03</th>
</tr>
</thead>
<tbody>
<tr>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>□</td>
</tr>
</tbody>
</table>

Your present meters are:

- Accuracy of conductivity and temperature of the meter is higher than MAAI Suitable in accordance with the guidelines of ISO 10012-1
- Accuracy of conductivity or temperature of the meter is below MAAI Not suitable in accordance with the guidelines of ISO 10012-1

Conclusion

Why take a risk? Use only meters which are suitable in accordance with the guidelines of ISO 10012-1. The high quality meters from IBP may be used with any type of dialysis machine.
You’ve properly calibrated your dialysis meter and then calibrate a dialysis machine using the meter. This means that the machine will be accurately calibrated, right? Not necessarily.

The Temperature Coefficient

A solution’s conductivity will change according to temperature. With increasing temperatures, the measured solution’s conductivity will increase, too. To achieve meaningful measurement results, the conductivity value displayed on your meter is compensated to 25°C. In other words, the display is always converted to a solution temperature of 25°C. The temperature coefficient which the displayed value is compensated with is expressed as %/°C. Unfortunately however, different solutions also have different temperature coefficients. To achieve an exact display, the meter will have to be adjusted to the temperature coefficient of the current solution. The average temperature coefficient for dialysates is 2.07 %/°C. Unfortunately, most meters (except the models made by IBP Medical) do not have adjustable temperature coefficients.

For naturally occurring solutions, a value of 1.97 %/°C is frequently used. Many measuring devices not specially tailored to dialysis will use this value. The calculations below show the drastic effects of an incorrect temperature coefficient.

Example calculation for an incorrect temperature coefficient, using a dialysate with a temperature coefficient of 2.07 %/°C:

<table>
<thead>
<tr>
<th>Conductivity of Solution</th>
<th>Temperature of Solution</th>
<th>Coefficient of Instrument</th>
<th>Display of Instrument</th>
<th>Difference in Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 ms/cm</td>
<td>37 °C</td>
<td>2.07 %/°C</td>
<td>14.00 ms/cm</td>
<td>0.00 %</td>
</tr>
<tr>
<td>14 ms/cm</td>
<td>37 °C</td>
<td>1.97 %/°C</td>
<td>14.17 ms/cm</td>
<td>1.21%</td>
</tr>
</tbody>
</table>

Ask your nephrologist if he or she can accept a deviation of up to 3% in sodium. I would assume that most nephrologists would never tolerate this. Thus, our calculation example illustrates that the user must set the temperature coefficient correctly in order to ensure accurate conductivity.

Which temperature coefficient you should use?

If you have machines from one manufacturer, use the temperature coefficient that the dialysis machine uses for compensation. This information may be obtained from your manufacturer or the documentation that came with your dialysis machine.

If you have different types of dialysis machines in your unit the most practical solution is to use a temperature coefficient of 2.07 %/°C for all machines. This avoids confusion with different readings of conductivity on different machines.

The HDM97 and HDM99 from IBP Medical are the only dialysis meters offering a user-selectable temperature coefficient for the highest possible accuracy in machine calibrations.
Aren’t Conductivity Reference Solutions just water and salt?
Before pursuing the question in detail, some of the basic issues are listed below in order to comprehend the matters involved.

**Primary, Secondary Standards and Working Solutions**
All reference solutions used for dialysis must adhere to national standards. In the U.S.A. the NIST (National Institute of Standards and Technology) and for Germany the PTB (Physikalisch-Technische Bundesanstalt) is responsible for these standards.

**Primary Standards** are solutions that have been calibrated strictly according to the NIST or PTB standard measurement equipment.

**Secondary Standards** are solutions that have been calibrated with a measuring instrument adjusted with a Primary Standard.

**Working Solutions** are solutions that have been calibrated using a measuring instrument adjusted with a Secondary Standard.

Due to the error factors, measuring uncertainty will be continuously increased and with every step, the uncertainty of the current measuring system is added to the imprecision of the measured value. Thus, with each step further away from Primary Standards, less accuracy is achievable. By definition, the Primary Standard achieves the highest possible accuracy whereas the Working Solution is the least accurate.

**Uncertainty of Measurement**
It is nowadays customary to claim an accuracy of 0.5% (for example) for a solution. The measuring accuracy is usually determined simply by taking a series of measurements from the solution and determining the accuracy from the deviation between the measurements.

**What is uncertainty?**
In ordinary use the word “uncertainty” does not inspire confidence. However, when used in a technical sense as in “measurement uncertainty” or ‘uncertainty of a test result’ it carries a specific meaning. It is a parameter, associated with the result of a measurement (e.g. a calibration or test) that defines the range of the values that could reasonably be attributed to the measured quantity. When uncertainty is evaluated and reported in a specified way it indicates the level of confidence that the value actually lies within the range defined by the uncertainty interval.

**How does it arise?**
Any measurement is subject to imperfections; some of these are due to random effects, such as short-term fluctuations in temperature, humidity and air-pressure or variability in the performance of the measurer. Repeated measurements will show variation because of these random effects. Other imperfections are due to the practical limits to which correction can be made for systematic effects, such as offset of a measuring instrument, drift in its characteristics between calibrations, personal bias in reading an analog scale or the uncertainty of the value of a reference standard.

**Why is it important?**
The uncertainty is a quantitative indication of the quality of the result. It gives an answer to the question: How well does the result represent the value of the quantity being measured? It allows users of the result to assess its reliability, for example for the purposes of comparison of results from different sources or with reference values. Confidence in the comparability of results can help to reduce barriers to trade. Often, a result is compared with a limiting value defined in a specification or regulation. In this case, knowledge of the uncertainty shows whether the result is well within the the acceptable limits or only just makes it. Occasionally a result is so close to the limit that the risk associated with the possibility that the property that was measured may not fall within the limit, once the uncertainty has been allowed for, must be considered.

Suppose that a customer has the same test done in more than one laboratory, perhaps on the same sample, more likely on what they may regard as an identical sample of the same product. Would we expect the laboratories to get identical results? Only within limits, we may answer, but when the
results are close to the specification limit it may be that one laboratory indicates failure whereas another indicates a pass. From time to time accreditation bodies have to investigate complaints concerning such differences. This can involve much time and effort for all parties, which in many cases could have been avoided if the uncertainty of the result had been known by the customer.

The explanation above is also available at: [http://www.ukas.com/new_docs/technical-uncertain.htm](http://www.ukas.com/new_docs/technical-uncertain.htm).

More information on the subject of measuring uncertainty is available on the internet at following addresses:
- [http://www.measurementuncertainty.org](http://www.measurementuncertainty.org)

**Why use the measuring uncertainty?**

It’s the standard. NIST, PTB and all international organizations only use this way to publish the “accuracy.”

**Too complicated?**

To have a coarse approximation to the widely used “accuracy” divide the value of Uncertainty by 2.

**Examples:**
1. IBP Solution 14.00 mS/cm with a Combined Standard Uncertainty of ±0.15%.
   To get the “accuracy” divide the Uncertainty by two: Accuracy is about ±0.075%

2. A solution has an accuracy of 0.5%: This leads to a Uncertainty of about ±1%.

**National Standards**

The national standards for Conductivity Reference Solutions are defined by the different organizations and in some cases solutions are also available from them. In the USA, NIST ([http://www.nist.gov](http://www.nist.gov)) and in Germany, PTB ([http://www.ptb.de](http://www.ptb.de)).

There is a multinational agreement between the national institutes for the mutual acknowledgement of measuring results, the CIPM Mutual Recognition Arrangement (CIPM-MRA). This agreement was signed in 2000 ([http://kcdb.bipm.fr](http://kcdb.bipm.fr)).

The quality of the measuring results must be proven by international comparison, the so-called key comparisons. After passing extensive international test procedures, the measurement methods/possibilities of the individual institutes are published on the internet at [http://kcdb.bipm.fr](http://kcdb.bipm.fr).

The German PTB can give an absolute determination of the conductivity of solutions without calibration. The measurement uncertainty of these primary standards is better than ±0.15% and with a lower conductivity can even achieve values better than ±0.1%.

The NIST offers primary standards only in very restricted values. The other NIST Conductivity-SRMs are measured with this primary SRM (Standard Reference Materials) calibrated measuring cells and are, as a result, Secondary Standards. In the NIST calibration certificate papers, the value 10000 µS/cm is declared as having a measurement uncertainty of 0.27%.

**Reference Solutions are just water and salt?**

Correct, but to be precise, de-ionized water and depending on the solution either NaCl or KCl, too. NaCl is useful with reference-solution values from 2 mS/cm as the temperature-coefficient approaches that of the dialysate. KCl is used with low conductivity values. In order to guarantee the stability of the solution, the solutions must have the same carbon dioxide content as the ambient air.

Make no mistake, solutions with the unparalleled low measuring uncertainty offered by IBP are high tech, high precision products backed by years of careful research and international standards.
What people say about IBP Dialysis Meters

User - USA

I have serviced dialysis equipment for at least 16 years. I find that the HDM99 meter is the single most useful tool I have ever used in trouble shooting, repairing and calibrating dialysis equipment. I especially appreciate the fact that features offered on the HDM99 provide such precise output that I rely on my meter as an absolute "final word" in resolving calibration discrepancies. The HDM99 has proven to be an invaluable tool in verification of systems and algorithms used in the dialfiltration machine we have developed. The PC interface makes data acquisition and charting easy.

I do have one minor complaint in the form of a question: why didn't you provide such a great tool ten years ago?

Ed Spence
Nephros Inc.
eMail: Spence@Nephros.com

User - USA

Please accept our thanks for allowing Renal Care Group, Inc. to evaluate the IBP HDM97 Dialysis Meter. RCG has long been in search of a dialysate meter that combines the capabilities of accurately measuring conductivity, temperature, pressure, and pH with reliability and durability. In addition, to the aforementioned criteria, we have been searching for a dialysate meter that is functionally easy for our Biomedical Technicians to calibrate and maintain. We believe the IBP HDM97 meets or exceeds all these criteria. In my 22 years of experience, HDM97's accuracy is unprecedented particularly in regard to pH measurements. The conductivity cell's accuracy and durability are unparalleled as well. The HDM97 has forced us to redefine our thinking in regard to what is "State of the Art." Clearly, the HDM97 Meter sets the "Gold" standard for the dialysis industry. We look forward to using these meters throughout our system.

Finally, RCG looks forward to evaluating the HDM99-dialysate meter. We believe the added capabilities of the HDM99 will find significant use in our research departments thus facilitate RCG's plans to deliver the best and most optimal plan of care to our thousands of patients.

Mark M. Rolston,
RCG, Corporate Director of Technical Operations
eMail: mrolston@renalcaregroup.com

IBP distributor - United Kingdom:

First rate engineering has developed a pair of reference meters with class-leading specifications, unrivalled versatility and 100% reliability over the last two years. With few exceptions, customer evaluation of the HDM meter has resulted in immediate purchase. The ability to measure the conductivity of either RO water or dialysate; use of the flow meter to set RO output flow; and pressure readings displayed in various units are major attractions of the meters.

The calibration service is both quick and efficient, minimising down-time for our customers.

Peter Walton
LINC Medical Systems Ltd
eMail: peterwalton@linc-medical.co.uk
Probably the most valuable piece of equipment in the dialysis technicians armory of tools is the conductivity / temperature monitor. Technicians are expected to calibrate dialysis machines accurately and quickly, possibly at some distance from base. Laboratory results are not always reliable so reliance falls heavily on the conductivity / temperature monitor.

I have been asked to convey to you my experience with the HDM99 Dialysis measuring system. At the Lister we have been using one instrument for 18 months and now have a second.

The system consists of a Display unit, conductivity/temperature/pressure probe, pH probe, flow sensor, voltmeter, leads and power supply. Software is supplied which enables PC/notebook display and data logging via the monitors RS232 port. The whole system is housed in an aluminium carrying case with enough space for the tube, ‘Y’ pieces, connectors, adapters and syringes that become part of a kit.

The LCD display is easily readable and well organised with a digital, bargraph and graphical representation for each individual parameter. Up to 4 parameters can be displayed together in digital and bargraph format. The graphical display is a rough guide on the monitor but very good on a notebook. The parameters included are Conductivity, temperature, pressure, pH, flow, voltage - plot and oscilloscope, frequency

Conductivity ranges between 0 µS/cm to 20 mS/cm enabling use on RO water to dialyser fluid. The probe can be used in line or dip. Temperature ranges cover dialyse and hot rinse with no correction factor required for high temperatures. Parameter ranges and graph time bases can be individually set.

The system has vast capability and it takes some time to become conversant with all the facilities, however one facility that has enhanced routine maintenance is the recording of conductivity and temperature. During maintenance bicarbonate and acid concentrate mixing levels are checked and set. The HDM99 is set up to display on a laptop, the graphical display enabling rapid and accurate determination of correct settings. The session is recorded, displaying original levels, adjustments, and final levels. The complete recording is then saved to a file in the machine records along with the electrical safety test.

There is facility to interface with a dialysis machine directly via RS232 ports using a driver available from IBP. I have not had the time to investigate this facility yet.

Annual calibration involves returning the instrument to IBP; the turn round being within 2 weeks. A full comprehensive calibration certificate is issued guaranteeing temperature, pressure and voltage for one year and for conductivity and pH with monthly verification against standards. The monthly verification with the standards is quick and easy.

The graphical display and logging facility is particularly useful. Accuracy, confirmed by the monthly checks, appears to be good. The wealth of measuring parameters takes some time to become fully conversant with. The voltage plot, counter and oscilloscope, although useful for some measurements do not replace standalone instruments. A clamp to secure the monitor to the dialysis machine would be an improvement.

Overall I am very pleased with the monitor.

Richard Humber
Lister Renal Unit
## Dialysis Meters - Differences

### between IBP (HDM99XP and HDM97) and MESA Labs (90DX™ and NEO-2™) Meter

#### Conductivity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>HDM99XP</th>
<th>HDM97</th>
<th>90DX™</th>
<th>NEO-2™</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Range</strong></td>
<td>0 uS/cm ... 200 mS/cm</td>
<td>0 uS/cm ... 19.99 mS/cm</td>
<td>0 uS/cm ... 20 mS/cm</td>
<td>20 uS/cm ... 199.9 mS/cm</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>+/- 0.6 uS/cm</td>
<td>+/- 0.6 uS/cm</td>
<td>+/- 10 uS/cm</td>
<td>+/- 10 uS/cm</td>
</tr>
<tr>
<td>0 … 199.9 uS/cm</td>
<td>+/- 0.6 uS/cm</td>
<td>+/- 0.6 uS/cm</td>
<td>+/- 10 uS/cm</td>
<td>+/- 10 uS/cm</td>
</tr>
<tr>
<td>20 … 199 uS/cm</td>
<td>+/- 6 uS/cm</td>
<td>+/- 6 uS/cm</td>
<td>+/- 10 uS/cm</td>
<td>+/- 10 uS/cm</td>
</tr>
<tr>
<td>1 … 2 mS/cm</td>
<td>+/- 0.1 mS/cm</td>
<td>+/- 0.1 mS/cm</td>
<td>+/- 0.1 mS/cm</td>
<td>+/- 0.1 mS/cm</td>
</tr>
<tr>
<td>2 … 19.99 mS/cm</td>
<td>+/- 0.03 mS/cm</td>
<td>+/- 0.03 mS/cm</td>
<td>+/- 0.1 mS/cm</td>
<td>+/- 0.1 mS/cm</td>
</tr>
<tr>
<td>20 … 24 mS/cm</td>
<td>+/- 0.06 mS/cm</td>
<td>+/- 0.06 mS/cm</td>
<td>+/- 0.1 mS/cm</td>
<td>+/- 0.1 mS/cm</td>
</tr>
<tr>
<td>20 … 99 mS/cm</td>
<td>+/- 0.3 mS/cm</td>
<td>+/- 0.3 mS/cm</td>
<td>+/- 0.1 mS/cm</td>
<td>+/- 0.1 mS/cm</td>
</tr>
<tr>
<td>100 … 199 mS/cm</td>
<td>+/- 0.6 mS/cm</td>
<td>---</td>
<td>---</td>
<td>+/- 2 mS/cm</td>
</tr>
</tbody>
</table>

#### Temperature

<table>
<thead>
<tr>
<th>Parameter</th>
<th>HDM99XP</th>
<th>HDM97</th>
<th>90DX™</th>
<th>NEO-2™</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Range</strong></td>
<td>0 … 100 °C</td>
<td>0 … 100 °C</td>
<td>15 … 90 °C</td>
<td>10 … 90 °C</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>+/- 0.1 °C</td>
<td>+/- 0.1 °C</td>
<td>+/- 0.2 °C</td>
<td>+/- 0.2 °C</td>
</tr>
<tr>
<td>0 … 15°C</td>
<td>+/- 0.1 °C</td>
<td>+/- 0.1 °C</td>
<td>+/- 0.2 °C</td>
<td>+/- 0.2 °C</td>
</tr>
<tr>
<td>15 … 40°C</td>
<td>+/- 0.1 °C</td>
<td>+/- 0.1 °C</td>
<td>+/- 0.2 °C</td>
<td>+/- 0.2 °C</td>
</tr>
<tr>
<td>10 … 40°C</td>
<td>+/- 0.05 °C</td>
<td>+/- 0.1 °C</td>
<td>+/- 0.2 °C</td>
<td>+/- 0.2 °C</td>
</tr>
<tr>
<td>40 … 90°C</td>
<td>+/- 0.1 °C</td>
<td>+/- 0.1 °C</td>
<td>+/- 0.2 °C</td>
<td>+/- 1 °C</td>
</tr>
</tbody>
</table>

#### Pressure

<table>
<thead>
<tr>
<th>Parameter</th>
<th>HDM99XP</th>
<th>HDM97</th>
<th>90DX™</th>
<th>NEO-2™</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Range</strong></td>
<td>-700 ... 1600 mmHg</td>
<td>-700 ... 1600 mmHg</td>
<td>-700 ... 1000 mmHg</td>
<td>-700 ... 1000 mmHg</td>
</tr>
<tr>
<td><strong>Differential</strong></td>
<td>+/- 1 mmHg</td>
<td>+/- 3 mmHg</td>
<td>+/- 2 mmHg</td>
<td>+/- 1% of reading</td>
</tr>
<tr>
<td>+/ - 200 mmHg</td>
<td>+/- 1 mmHg</td>
<td>+/- 3 mmHg</td>
<td>+/- 2 mmHg</td>
<td>+/- 1% of reading</td>
</tr>
<tr>
<td>&lt; -200 and &gt;200 mmHg</td>
<td>+/- 0.5 mmHg</td>
<td>+/- 0.5 mmHg</td>
<td>+/- 0.5 mmHg</td>
<td>+/- 0.5 mmHg</td>
</tr>
</tbody>
</table>

#### pH

<table>
<thead>
<tr>
<th>Parameter</th>
<th>HDM99XP</th>
<th>HDM97</th>
<th>90DX™</th>
<th>NEO-2™</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Range</strong></td>
<td>1 … 14 pH</td>
<td>1 … 14 pH</td>
<td>0 … 14 pH</td>
<td>1 … 12 pH</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>+/- 0.02 pH</td>
<td>+/- 0.02 pH</td>
<td>+/- 0.07 pH</td>
<td>+/- 0.1 pH</td>
</tr>
</tbody>
</table>

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### Important to know

- Flow: ✓ ✓ ✓ ✓ ✓
- Voltage: ✓ ✓ ✓ ✓ ✓
- Frequency: ✓ ✓ ✓ ✓ ✓
- Counter: ✓ ✓ ✓ ✓ ✓
- Timer: ✓ ✓ ✓ ✓ ✓
- RS232: ✓ ✓ ✓ ✓
- Rechargable NIMH-Battery: ✓ ✓ ✓ ✓
- Manufactured under certified ISO9001 Quality Management: ✓ ✓ ✓ ✓
Does IBP offer calibration service for instruments from other manufacturers?

Yes we do. IBP offers a calibration service to ISO9000 standards for the measurement parameters of conductivity, temperature, pressure, pH and flow. Instruments from other manufacturers will now also be calibrated besides the instruments produced by IBP.

The calibration service is precisely matched to the needs encountered in dialysis. The calibration points are fixd in such a way that the measurement on dialysis machines can be carried out with the utmost precision. For example, temperature and pressure are calibrated at a minimum of two measurement points in each measuring range. For the calibration we use reference solutions based on NIST and PTB and supplied with a DKD calibration certificate. A comprehensive calibration certificate is drafted from the data collected. The instrument is given a calibration sticker, which documents the validity of the calibration.

Does IBP have a quality management system?

Yes we have. We have been ISO9001 certified since July 2000. The certification was conducted by MedCert, a company which specialises in certifying companies in the field of medical technology.

The preparations took around 6 months. To prepare the quality management manual, all operational sequences were analyzed and partly restructured. In the course of implementing the quality management system, the restructuring and optimization of procedures in the development, production and administration departments was an intended side effect.

Is it possible to measure RO Water with the HDM97 or HDM99XP?

Yes it is. The IBP meters are the only dialysis meters which have a measuring range beginning at 0 uS/cm. With the accuracy of +/- 0.6 uS/cm the IBP meters are the only devices which measure RO water with the needed high accuracy.
RenalChair

The RenalChair 2000 is the perfect solution for dialysis and limited-care treatment. The chair is wide enough to enable the patient to sleep in total comfort. The chair’s three positioning motors and convenient hand control provide the flexibility and technology seen only previously in luxury automobiles and first class airline seats. The RenalChair 2000 truly provides first class patient accommodations.

HDW5

Heat exchanger for hemodialysis machines for easy subsequent fitting to all dialysis machines. The material is especially suitable for the purpose and resistant to chemical and heat desinfection. Optimized heat exchange for fast amortization.

Also a service from IBP

NephroWorld, one of the most visited dialysis-related web sites. Read the daily news and follow thousands of interesting links.

www.nephroworld.com

Innovation and quality have no borders

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HDM97 - HDM99XP

Highly accurate meters for measurement of:
- Conductivity
- Temperature
- Pressure
- pH
- Flow
- Voltage
- Frequency
- Period Time
- Pulses